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Tebuthiuron Summary Document
Registration Review: Initial Docket
September 2009

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Case # 0054

Approved By:

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Date

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Please Note

This Preliminary Work Plan (PWP) and Fact Sheet summarize the Environmental Protection Agency's current position based on the following documents:

1. Registration Review—Preliminary Problem Formulation for the Ecological Risk and Environmental Fate, Endangered Species and Drinking Water Assessments for Tebuthiuron (PC Code 105501; DP Barcode (D363982). June 15, 2009.

2. Tebuthiuron. Registration Review Scoping Document for Human Health Assessment. July 23, 2009.

3. Tebuthiuron (105501) California DPR Usage Data. January 8, 2009.

4. Appendix A: Food/Feed & Non-Food/Non-Feed Uses Considered in Registration Review Work Planning. Tebuthiuron ((105501) Case No. 0054. October 31, 2008.

Additional supporting documents for tebuthiuron may be found in the docket EPA-HQ-OPP-2009-0327, located on the internet at www.regulations.gov.

I. Preliminary Work Plan – Tebuthiuron

Introduction:

The Food Quality Protection Act (FQPA) of 1996 mandated the registration review program. All pesticides distributed or sold in the United States generally must be registered by the U.S. Environmental Protection Agency (USEPA, EPA, or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at <http://www.epa.gov/oppsrrd1/registration_review/>.

The Agency is implementing the registration review program, and will review each registered pesticide every 15 years to determine whether it continues to meet the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of tebuthiuron.

Tebuthiuron is a systemic, relatively nonselective urea herbicide which is absorbed into the plant roots and is then translocated into the plant. Once absorbed and translocated into the plant, it acts by inhibiting photosynthesis. It is registered for use to control broadleaf and woody weeds, grasses and brush on feed crop sites. Primary use sites include rangeland, near railroads, and other industrial facilities. There are no residential or public recreational uses for tebuthiuron. Compound 104, the toxicological degradate of concern, is assumed to have equivalent toxicity to tebuthiuron parent because of its structural similarity to its parent compound.

Anticipated Risk Assessment and Data Needs:

The Agency anticipates conducting a comprehensive ecological risk assessment, including an endangered species assessment, for all pesticide uses of tebuthiuron. The Agency anticipates conducting a human health risk assessment.

Ecological Risk:

- The most recent ecological assessment was completed in 1994 in support of the Tebuthiuron Reregistration Eligibility Decision (RED).

- The Agency has not conducted a risk assessment that supports a complete endangered species determination. The ecological risk assessment planned during registration review will allow the Agency to determine whether tebuthiuron's use has "no effect" or

"may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Services (the Services), as appropriate.

- For the ecological assessment, the Agency will consider parent tebuthiuron only, based on environmental fate data; compound 104 is not formed in sufficient amounts to affect risk conclusions.

- The Agency anticipates requiring the following data for parent tebuthiuron in order to conduct a complete ecological risk assessment for tebuthiuron, including an endangered species assessment:

    - OPPTS GLN 835.6200 Aquatic field dissipation
    - OPPTS GLN 850.1075 Marine/estuarine fish acute toxicity
    - OPPTS GLN 850.1025; 850.1055 Bivalve acute toxicity on shell deposition and embryo larvae
    - OPPTS GLN 850.1035; 850.1045 Crustacean acute toxicity
    - OPPTS GLN 850.1400 Freshwater fish early-life stage toxicity
    - OPPTS GLN 850.1300 Aquatic invertebrate life cycle
    - OPPTS GLN 850.4100 Tier II Seedling emergence toxicity
    - OPPTS GLN 850.4150 Tier II Vegetative vigor
    - OPPTS GLN 850.2100 Avian acute oral toxicity study testing a passerine species
    - OPPTS GLN 850.2200 Avian reproductive toxicity study (testing exposure concentrations ranging from > 100 ppm to at least up to 810 ppm)

- Refer to the document, *Registration Review Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Tebuthiuron*, located in the docket, for a detailed discussion of the anticipated ecological risk assessment needs.

Human Health Risk:

- The most recent dietary risk assessment was conducted in April 2002 in support of the Tebuthiuron Tolerance Reassessment Eligibility Decision (TRED).

- The Agency anticipates conducting a new dietary assessment for tebuthiuron.

- Since the Agency plans to update the drinking water exposure assessment for tebuthiuron to directly incorporate drinking water residues into the dietary risk assessment (food and water), a cumulative residue approach will be applied to model total tebuthiuron residues (tebuthiuron parent plus compound 104) for the drinking water assessment in registration review.

- The Agency anticipates conducting a reevaluation of the total dietary burden for beef and dairy cattle using feedstuffs to support the reassessment of established

tebuthiuron tolerances on animal commodities, as outlined in OPPTS Guideline Test Series 860, Table 1 circa June 2008.

- There are currently no residential or public recreational uses for tebuthiuron; therefore, the Agency will not be conducting a residential assessment.

- Occupational exposures have not been considered quantitatively in any existing risk assessment to date for tebuthiuron; however, given the use patterns, occupational exposures can occur. Therefore the Agency anticipates conducting, an occupational handler risk assessment in registration review based on the current tebuthiuron use patterns.

- Postapplication worker exposures are not expected to occur because tebuthiuron is applied to sites where reentry is unlikely. An assessment for these type of tasks has not been completed and would not be warranted unless use patterns change in the future.

- The Agency anticipates requiring the following data for parent tebuthiuron in order to conduct a complete human health risk assessment for tebuthiuron:

  - The Agency anticipates requiring confined field rotational crop studies (GLN 860.1900) unless the registrant provides information that demonstrates to the Agency that the pastureland use area is either insignificant in acreage or is predominantly perennial grasses that are not rotated annually.
  - The Agency anticipates requiring an immunotoxicity study (GLN 870.7800). This is a new data requirement under 40 CFR Part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses).
  - The Agency anticipates requiring a neurotoxicity battery (acute and subchronic studies) (GLN 870.6200). The neurotoxicity studies will provide scientific information that is needed to evaluate the potential adverse effects on the nervous system from exposure to pesticide.
  - Since the 2002 TRED, EPA received the requested mammalian erythrocyte micronucleus test study (GLN 870.5385). Upon review of that study, EPA will evaluate the mutagenic potential of tebuthiuron.

- Upon receipt, and review of the anticipated data, the Agency will reevaluate the points of departure and uncertainty factors for the dietary assessments.

- Please refer to the document, Tebuthiuron – *Registration Review Scoping Document for Human Health Assessments*, located in the docket, for a detailed discussion of the anticipated risk assessment needs for human health.

Timeline:

EPA has created the following estimated timeline for the completion of the tebuthiuron registration review.

Registration Review for Tebuthiuron Projected Registration Review Timeline	
Activities	**Estimated Year/Month**
Opening the Docket	
Open Docket and Public Comment Period for Preliminary Work Plan	September 2009
Close Public Comment Period	November 2009
Case Development	
Final Work Plan	January 2010
Issue Data Call-In	Oct. – Dec. 2010
Data Submission	Oct. – Dec. 2012
Open Public Comment Period for Preliminary Risk Assessments	Apr. – June 2014
Close Public Comment Period	July -- Sept. 2014
Registration Review Decision	
Open Public Comment Period for Proposed Registration Review Decision	Oct. – Dec. 2014
Close Public Comment Period	Jan. – Mar. 2015
Final Registration Review Decision and Begin Post-Decision Follow-up	2015
Total (years)	**6**

Guidance for Commenters:

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided in a timely manner prior to issuing a final work plan for the tebuthiuron registration review case.

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Tebuthiuron is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885. In addition, no Total Maximum Daily Loads (TMDL) have been developed for tebuthiuron, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES. More information on impaired water bodies and TMDLs can be found at http://www.epa.gov/owow/tmdl/. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process* (see: http://www.epa.gov/oppfead1/cb/ppdc/2006/november06/session1-

sop.pdf), in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to tebuthiuron compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

Stakeholders are also specifically asked to provide information and data that will assist the Agency in refining the ecological and human health risk assessments, including any species-specific effects determinations. The Agency is interested in obtaining the following information regarding the use of tebuthiuron:

1. use or potential use distribution (e.g., acreage and geographical distribution of relevant crops)
2. use history
3. median and 90th percentile reported use rates (lbs ai/acre) from usage data – national, state, and county
4. application timing (date of first application and application intervals) by crop – national, state, and county
5. sub-county crop location data
6. directly acquired county-level usage data (not derived from state level data)
   a. maximum reported use rate (lbs ai/acre) from usage data – county
   b. percent crop treated – county
   c. median and 90th percentile number of applications – county
   d. total pounds per year – county
   e. the year the pesticide was last used in the county/sub-county area
   f. the years in which the pesticide was applied in the county/sub-county area
7. state or local use restrictions
8. ecological incidents (non-target plant damage and avian, fish, reptilian, honey bee, amphibian and mammalian mortalities) not already reported to the Agency
9. monitoring data

Next Steps:

After the 60-day comment period closes, the Agency will review and respond to any comments received in a timely manner, and then issue a Final Work Plan for this pesticide.

II. FACT SHEET: Tebuthiuron Registration Review

Background Information:

- Tebuthiuron registration review case number: 0054
- Tebuthiuron Pesticide Chemical (PC) Code: 105501
- Tebuthiuron CAS number: 34014-18-1
- There are eleven products registered under FIFRA Section 3.
- Technical Registrants: Dow AgroScience LLC, Celsius Property B.V., Amsterdam (NL)
- The Reregistration Eligibility Decision (RED) for tebuthiuron was issued in 1994.
- The Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (TRED) for tebuthiuron was issued in 2002.
- Pesticide Re-evaluation Division (PRD), Chemical Review Manager (CRM) Wilhelmena Livingston: livingston.wilhelmena@epa.gov.
- Registration Division (RD), Product Manager (PM) Jim Tompkins: tompkins.jim@epa.gov.

Use & Usage Information: (For additional details, please refer to the Biological and Economic Analysis Division (BEAD) *Screening Level Usage Analysis (SLUA)* and *Appendix A* document in the tebuthiuron docket.)

- Tebuthiuron is a relatively nonselective, soil activated herbicide that acts by inhibiting photosynthesis. It is registered for use to control broadleaf and woody weeds, grasses, and brush on terrestrial feed crop sites (pastures and rangeland), and on terrestrial non-food crop sites [airports/landing fields, industrial areas (outdoor), non-agricultural rights-of-way/fencerows/hedgerows, non-agricultural uncultivated areas, and under newly applied asphalt and concrete].
- There are no residential or public recreational uses for tebuthiuron.
- Publicly available data from the California Department of Pesticide Regulation (CA DPR) indicates that over the three most recent years available (2004 – 2006), approximately 8,000 – 10,500 pounds of tebuthiuron were used in California.
- Tebuthiuron is formulated as a pellet/tablet, wettable powder, and a granular.
- Tebuthiuron, formulated as a pellet/tablet, is applied as a broadcast treatment using aerial or ground equipment, and may also be applied as a spot treatment. When formulated as a

wettable power, tebuthiuron is applied as a broadcast or banded treatment using ground equipment. Tebuthiuron may also be applied as a spot treatment using a hand-held spray.

Recent Actions

- There are no recent actions for tebuthiuron.

Ecological Risk Assessment Status:

Refer to the document, *Registration Review – Preliminary Problem Formulation for Ecological Risk and Environmental Fate, Endangered Species and Drinking Water Assessments for Tebuthiuron, June 15, 2009*, for the key findings of the previous ecological risk assessment.

- The 1994 RED concluded that tebuthiuron may pose significant risk to off-site endangered terrestrial, semi-aquatic, and aquatic plant species.

- In July 2004, a Tier II Aquatic Exposure Assessment was completed for selected tebuthiuron uses on rangeland, pastureland, and other non-crop lands in the Pacific Northwest in support of an Endangered Species Consultation Package. A Tier II Aquatic Exposure Assessment was also completed for selected tebuthiuron uses (carrots, alfalfa, cotton, grapes, safflower, and tomatoes) in California to support an Endangered Species Consultation package for salmon.

Human Health Risk Assessment Status:

Please refer to the document, *Tebuthiuron: Registration Review Scoping Document for Human Health Assessment, July 23, 2009,* in the docket, for a detailed discussion of the human health assessment. The following are key findings of the most recent human health risk assessment conducted in 2002 in support of the reassessment of the tolerances under FQPA.

Hazard Characterization:

The human health risk assessment for the TRED identified a number of toxicity data gaps. The data gaps included a developmental toxicity study in the rabbit, as well as a chronic feeding/carcinogenicity study in the rat and oncogenicity study in the mouse; these studies were previously submitted, but were found to be unacceptable. An in vivo bone marrow cytogentic assay was needed to evaluate the mutagenic potential of tebuthiuron. A 28-day inhalation study in the rat was required to characterize the effects of tebuthiuron via the inhalation route. Furthermore, the requirement for a development neurotoxicity study was held in reserve, pending the submission of the rabbit developmental toxicity study.

Since the 2002 TRED, the Agency received waiver requests from the registrant to reconsider the need to repeat the rat and mouse cancer studies. In response to that request, the Agency reevaluated the need for the additional rat and mouse cancer data, and concluded that there was adequate evidence that tebuthiuron was tested at high enough doses in the rat chronic/cancer study and that no additional data were needed to satisfy this guideline (OPPTS 870.4300). The Agency also determined that very little value would be added to the knowledge of the toxicity of tebuthiuron by repeating the mouse cancer/chronic study, especially considering the low human

exposure expected from the registered uses. Therefore, the Agency waived the requirement for the rat and mouse cancer/chronic studies. The Agency also indicated that, due to certain science policy changes, the developmental toxicity study in a nonrodent, the 28-day inhalation study, and the developmental neurotoxicity study are no longer required.

- Tebuthiuron is more toxic for oral (Toxicity Category II) exposure than for dermal (Toxicity Category IV) or inhalation (Toxicity Category III). Tebuthiuron is not an eye or skin irritant and is not a skin sensitizer.

- Tebuthiuron is classified as a Group D Carcinogen – not classifiable as to human carcinogenicity based on the lack of evidence for carcinogenic potential in mice and rats.

Dietary Risk (Food):

The only source of dietary (food) exposure is the consumption of secondary residues in meat and milk for livestock that is fed tebuthiuron-treated grass forage, hay, pasture and range land. The current tolerances were established using adequate feeding study data that were relative to the maximum theoretical dietary burden of tebuthiuron for beef cattle and diary cattle (OPPTS Guideline Test Series 860, Table 1).

- The acute and chronic dietary risk estimates were below the Agency's level of concern.

- The Agency has not identified any acute or chronic risk concerns from exposure to tebuthiuron in drinking water. A cumulative residue approach was used to model total tebuthiuron residues (parent and Compound 104 [the toxicological residue of concern] for drinking water assessment purposes.

Residential Risk:

- Tebuthiuron is neither registered for home use nor is it used in and around schools, parks or other areas where children are likely to be present. Therefore, a residential risk assessment was not performed.

Aggregate Risk:

- The aggregate risk assessment risk only included food and water, as there were no residential uses for tebuthiuron. There were no aggregate risks of concern.

Occupational Risk:

- Occupational exposures have not been considered quantitatively in any existing risk assessment to date for tebuthiuron. The Agency has determined that occupational handlers could be exposed during the following activities:

  o Loading granules for tractor drawn spreader application;
  o Loading pellets for tractor drawn spreader application;
  o Loading pellets for aerial application;

- Mixing/loading Dry Flowable for aerial application;.
- Mixing/loading Dry Flowable for groundboom application;
- Mixing/loading Dry Flowable for rights-of-way application;
- Mixing/loading/applying Dry Flowable for handgun application;
- Mixing/loading/applying Dry Flowable for low pressure handwand application;
- Loading/applying granular for application with belly grinder;
- Loading/applying granular for application with push-type spreader;
- Applying granular by shaker can;
- Applying granular by hand;
- Loading/applying pellets for application with belly grinder;
- Loading/applying pellets for application with push-type spreader;
- Applying pellets by shaker can; and
- Applying pellets by hand.

- Postapplication worker or bystander exposures to tebuthiuron are not expected to occur because tebuthiuron is applied to sites where reentry is unlikely.

Cumulative Risk Assessment:

- The Food Quality Protection Act (FQPA) requires the Agency to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. The Agency has not determined if there are any other chemical substances that have a common mechanism of toxicity with tebuthiuron. If the Agency identifies other substances that share a common mechanism of toxicity with tebuthiuron, the Agency will perform aggregate exposure assessments on each chemical, and will begin to conduct a cumulative risk assessment. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs on EPA's website at http://www.epa.gov/pesticides/cumulative/.

Incident Reports:

Human Incidents:

- The OPP's Incident Data System (IDS) reports 3 incidents occurring in the United States from 2002 to the present for tebuthiuron. In these 3 incidents, symptoms appear generic and not confirmed to be related to exposure to tebuthiuron. The symptoms include: a rash, pruritus, bullae/blisters, erythernal/flushed, nausea, confusion, and Dyspnea. Refer to the document, *Updated Review of Tebuthiuron Incident Reports*, for a detailed discussion of the human health incidents.

Ecological Incidents:

- A preliminary review of the Ecological Incident Information System (EIIS) maintained by the Agency indicated that there were four incidents that involved damage to terrestrial plants from the use of tebuthiuron. Two incidents were attributed to misuse, one incident was to a registered use, and another incident was undetermined.

Tolerances and International Harmonization:

- Tolerances for tebuthiuron are listed under 40 CFR §180.390.
- There are no maximum residue limits (MRLs) for residues of tebuthiuron in/on various raw agricultural and processed commodities established through Codex. Therefore, issues of compatibility with respect to U.S. tolerances and Codex MRLs do not exist.

Data Call-In Status:

The most recent generic Data Call-In (DCI) for tebuthiuron was issued on March 17, 2005 (GDCI-105501-17896). This DCI outlined the TRED confirmatory data requirements.

Labels:

A list of the current registration numbers are listed below and the labels can then be obtained from the Pesticide Product Label System (PPLS) website (<http://oaspub.epa.gov/pestlabl/ppls.home>).

Active Registrations for
Tebuthiuron

Registration Number	Registration Name	Company Name
13283-18	RAINBOW WEED KILLER 4037	RAINBOW TECHNOLOGY CORP
13283-21	RAINBOW WEED KILLER 4049	RAINBOW TECHNOLOGY CORP
34913-10	SPRAKIL S-5 BRUSH CONTROL GRANULES	SSI MAXIM COMPANY, INC.
34913-15	SPRAKIL SK-13 GRANULAR WEED KILLER	SSI MAXIM COMPANY, INC.
34913-16	SPRAKIL SK-26 GRANULAR WEED KILLER	SSI MAXIM COMPANY, INC.
62719-107	SPIKE 80DF	DOW AGROSCIENCES LLC
62719-109	SPIKE TECHNICAL	DOW AGROSCIENCES LLC
62719-121	SPIKE 20P	DOW AGROSCIENCES LLC
62719-122	SPIKE 40P	DOW AGROSCIENCES LLC
81927-37	ALLIGARE TEBUTHIURON 80 WG	ALLIGARE, LLC

83558-33	TEBUTHIURON TECHNICAL	CELSIUS PROPERTY B.V., AMSTERDAM (NL)